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Patents ADP number *(if you know it)* — 7998941001

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IMPROVEMENTS IN AND RELATING TO SURGICAL IMPLANTS

This invention concerns improvements in and relating to surgical implants, particularly, but not exclusively in relation to surgical implants for the replacement of intervertebral discs in the lumbar region of the spine.

Increasingly there is a desire to address problems with intervertebral discs by replacing all or part of the disc with a prosthetic disc rather than fusing the adjacent vertebrae. A wide variety of designs of disc prostheses exist. Generally they are based upon either articulated metal plates or metal end plates with a polyethylene spacer. Generally such devices face problems in terms of the reduced mobility they provide, are reliant upon absolutely correct positioning and do not emulate fully the normal motion they aim to replace.

Previously there has been developed a disc prosthesis including an element of elastomeric or visco-elastic material, the element being provided in a retaining fabric, US-6093205. The disc prosthesis was particularly developed for use in the cervical region of the spine.

The present invention has amongst its aims to provide an improved partial or total spinal disc replacement, particularly in the lumber region. The present invention has amongst its aims to provide a more reliable spinal disc replacement, particularly for the lumbar region.

According to a first aspect of the present invention we provide a disc prosthesis including a core, the core being provided within an inner component, the inner component being provided within an outer component.

The core may be a single component. The core may be formed of multiple components. A single or multiple components may be provided within an inner component, such as a jacket. Where multiple components are used it is preferred that each is provided within its own inner component. The component(s) may be blocks, beads, spheres, cylinders, rods or other such elements.

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The core may be formed of a single material type or of multiple material types. The core may be an elastomeric material. The core may be a visco-elastic material. The core may be a hydrogel, particularly an elastomeric one. The core may include silicone based materials. The core may include materials having a Shore A hardness of 35 to 80°. The core may be impregnated and/or doped and/or provided with further materials. The further materials may be or include barium sulphate.

Preferably the core provides equivalent properties and/or behaviour to the nucleus pulposus of a natural disc, for instance during compression and/or distraction and/or horizontal gliding and/or axial rotation and/or flexion and/or extension.

The core may provide a planar top surface and/or planar lower surface. The area of the top surface may be the same as the area of the lower surface. Preferably the top and bottom surfaces are not parallel to one another. Preferably the separation of the top and bottom surfaces increases from one side of the core to the other. Preferably the rate of increase in separation is even. Preferably the separation of the top and bottom surfaces increases from the anterior to the posterior side of the core. The top surface and/or bottom surface of the core may be octagonal and/or hexagonal and/or round and/or elliptic. The shape may be regular or irregular, for instance one or more sides of a octagon being larger than one or more others. Rounded corners to the shape are preferably provided.

The core is preferably provided with one or more sides extending between the top surface and the bottom surface. One, six or eight sides may particularly be provided. Where multiple sides are provided, preferably the pairs of opposing sides are provided. The sides may directly or indirectly oppose one another. Preferably opposing sides are parallel to one another, but potentially off set. Preferably the sides are planar. The sides may be vertically provided in use. The anterior side of the core may be of greater width than the posterior side of the core. The anterior side of the core may be of lesser height than the posterior side of the core. The edge of a side closer to the anterior side of the core may be shorter than the edge closer to the posterior side of the core.

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The core may be narrower towards the anterior side than towards the middle thereof and/or the core may be narrower towards the posterior side than towards the middle thereof. From anterior to posterior side, the core may have a portion of increasing width, a portion of constant width and a portion of decreasing width.

The core is preferably narrower in the anterior to posterior direction than it is wide, that is perpendicular to the anterior to posterior direction.

The interface between sides of the core and/or between the sides and bottom of the corer and/or between the sides and top of the core may be curved.

A particularly preferred form of the core is octagonal in cross-section, increases in thickness from the anterior side to the posterior side and has a shorter anterior side than posterior side. Preferably when viewed in plan, the core lies entirely within the plan of the disc it is to be used to replace.

The inner component may be an inner jacket. The inner component may be of fabric.

The fabric may be formed by flat or circular weaving, knitting, braiding, embroidery or combinations thereof.

The fabric may be formed using one or more of polyester, polypropylene, polyethylene, carbon fibre, glass fibre, glass, polyaramide, metal, copolymers, polylactic acid, polyglycolic acid, biodegradable materials, silk, cellulose or polycaprolactone.

Preferably the inner component is separate from the core. Preferably the inner component is separate from the outer component. Relative movement may be facilitated between the inner and outer components. Relative movement between the inner component and core may be allowed. Preferably movement between the inner and outer components is greater than between the inner component and core. Preferably movement between the inner and outer components is facilitated in preference to movement between the inner component and core. Preferably any

movement, particularly sliding movement, within the disc is greater between the outer component and inner component than between the inner component and core.

The inner component may entirely surround the core and/or encapsulate the core. One or more apertures or gaps are preferred in the inner component, ideally to provide fluid communication through the inner component. Preferably a large number of apertures or gaps are provided the material from which the inner component is formed, for instance a woven fabric. The apertures or gaps occurring in the inner component due to the manner of manufacture of the material from which it is formed may be supplemented with further apertures or gaps. The supplementation may be provided by degradation and/or absorption of one or more materials forming the inner component.

The inner component may be configured and/or formed of one or more materials intended to promote tissue growth, particularly tissue ingrowth between the inner component and the core and/or through the inner component.

One or more materials used in the inner component may be bio-absorbable. The bio-absorbable material may be used to decrease the amount of inner component present and/or positions at which the inner component is present and/or density at which the inner component is present overtime. Areas of bio-absorbable material may be provided. Bio-absorbable fibres may be used to form the inner component. The inner component may be entirely bio-absorbable or only partially. Different materials having different rates of bio-absorption may be used. The may be mixed together in the inner component and/or may be used for particular areas thereof and/or in a particular sequence within the inner component. Slow, moderate and fast bio-absorption materials may be used. Preferably bio-absorption of the inner component is used to provide space for tissue ingrowth.

Preferably the inner component provides a smooth inner surface which potentially contacts the core. Preferably uniform contact between the inner surface of the inner component and the core is provided. Preferably the fibres forming the inner surface of the inner component are evenly positioned with respect to one another. Preferably any abrasion of the core by the inner component is distributed rather than localised.

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The inner component preferably provides a smooth inner fabric surface, and ideally woven fibrous surface. A densely packed material may be used for the inner surface, ideally to provide the uniform contact surface with the core. The inner surface of the inner component may be of a different material and/or different configuration to the inside and/or outer surface of the inner component.

The inner component may be formed from a substantially planar element. The inner component may be so formed by folding and/or stitching and/or interdigitating one or more parts thereof. In particular, a top wall of the inner component may be connected to a side wall and hence to a bottom wall. One or more further side walls may be connected to the top wall and/or side wall and/or bottom wall. A series of side walls may be provided by an elongate part of the element. Folds or future folds may define one side wall relative to an adjacent side wall or walls.

In a preferred form, the inner component is formed from an element including a side wall connected on one edge to a top wall and connected on an opposing edge to a bottom wall. The respective edges of the side wall are preferably parallel. It is preferred that the side wall will form the side wall at either the anterior, or more preferably, posterior side. Preferably the side wall is connected on one side edge to one or more other side walls, ideally one. Preferably the side wall is connected on the other side edge to one or more other walls, ideally 4 in the case of a hexagonal core and 6 in the case of an octagonal core. The top and bottom edges of the side walls may be parallel or non-parallel depending upon the locations relative to the top and bottom walls they are to occupy. Preferably all the boundaries between side walls in the strip are parallel to one another.

Preferably the side wall(s), top wall and bottom wall are joined together by stitching and/or other attachment techniques.

One or more of the side walls of the inner component may be reinforced and/or of multiple thickness. The reinforcement or multiple thickness may be provided by an additional element provided outside of the side wall. The additional element for a side wall may be provided by wrapping one or more additional elements around the side walls. Preferably additional elements are provided for each side wall. Preferably

the additional elements are provided by a continuous band extending around the side of the inner component. Preferably the additional elements are configured to substantially match the dimensions of the side wall they contact.

In a preferred form, the additional elements are provided as a continuation of the element providing one or more of the side walls. Preferably the continuation provides 6 or 8 additional elements on the end of the 4 or 6 side walls it already provides.

The additional elements may be joined to the side walls and/or other parts of the inner component by stitching and/or other attachment techniques.

The side walls and/or additional elements may act as an annulus for the disc prosthesis. The side walls and/or additional elements may resists sideways expansion of the core, particularly when under compressive load. The side walls and/or additional elements may provide equivalent properties and/or behaviour to the annulus of a natural disc, for instance during compression and/or distraction and/or horizontal gliding and/or axial rotation and/or flexion and/or extension.

Preferably the core is provided snugly within the inner component. Preferably the top wall and/or bottom wall and/or one or more side walls of the inner component are dimensioned to contact the core.

The outer component may be an outer jacket. The outer component may be of fabric.

The fabric may be formed by flat or circular weaving, knitting, braiding, embroidery or combinations thereof.

The fabric may be formed using one or more of polyester, polypropylene, polyethylene, carbon fibre, glass fibre, glass, polyaramide, metal, copolymers, polylactic acid, polyglycolic acid, biodegradable materials, silk, cellulose or polycaprolactone.

The outer component may entirely surround the inner component and/or encapsulate the inner component. One or more apertures or gaps are preferred in the outer

component, ideally to provide fluid communication through the outer component. Preferably a large number of apertures or gaps are provided the material from which the outer component is formed, for instance a woven fabric. The apertures or gaps occurring in the outer component due to the manner of manufacture of the material from which it is formed may be supplemented with further apertures or gaps. The supplementation may be provided by degradation and/or absorption of one or more materials forming the outer component.

The outer component may be configured and/or formed of one or more materials intended to promote tissue growth, particularly tissue ingrowth through the outer component and/or between the inner component and the core and/or through the inner component.

One or more materials used in the outer component may be bio-absorbable. The bio-absorbable material may be used to decrease the amount of outer component present and/or positions at which the outer component is present and/or density at which the outer component is present overtime. Areas of bio-absorbable material may be provided. Bio-absorbable fibres may be used to form the outer component. The outer component may be entirely bio-absorbable or only partially. Different materials having different rates of bio-absorption may be used. The may be mixed together in the outer component and/or may be used for particular areas thereof and/or in a particular sequence within the outer component. Slow, moderate and fast bio-absorption materials may be used. Preferably bio-absorption of the outer component is used to provide space for tissue ingrowth.

Preferably the outer component provides a resilient and/or strong containment for the inner component and/or core. Preferably the outer component provides for the anchoring of the prosthesis to the spine.

The outer component may be formed from a substantially planar element. The outer component may be so formed by folding and/or stitching and/or interdigitating one or more parts thereof. In particular, a top wall of the outer component may be connected to a side wall and hence to a bottom wall. One or more further side walls may be connected to the top wall and/or side wall and/or bottom wall. A series of side walls

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may be provided by an elongate part of the element. Folds or future folds may define one side wall relative to an adjacent side wall or walls.

In a preferred form, the outer component is formed from an element including a side wall connected on one edge to a top wall and connected on an opposing edge to a bottom wall. The respective edges of the side wall are preferably parallel. It is preferred that the side wall will form the side wall at either the anterior, or more preferably, posterior side. Preferably the side wall is connected on one side edge to one or more other side walls, ideally two. Preferably the side wall is connected on the other side edge to one or more other walls, ideally 2 in the case of an octagonal core. A further side wall is preferably connected to the opposite edge of the top wall or bottom wall to the edge to which the side wall linking the top wall and bottom wall is provided. The top and bottom edges of the side walls may be parallel or non-parallel depending upon the locations relative to the top and bottom walls they are to occupy. Preferably all the boundaries between side walls in the strip are parallel to one another.

Preferably one or more edges of the top wall and/or one or more edges of the bottom wall are provided with flanges. Preferably a flange has a length greater than the height of the side walls and/or greater then height of the disc space in which the prosthesis is to be used. The flanges, particularly towards their ends may provide anchor locations for attaching the outer component to one or more vertebrae. The flanges may have a width less than the width of a side wall.

In a preferred form, a flange is provided on an edge of the top wall which opposes, ideally when considered in the assembled position, an edge of the bottom wall provided with a flange. One of the flanges may be provided with a through aperture. One of the flanges may be provided with a reduced width and/or neck part. Preferably one of the flanges is interdigitated with the other by passing it though the hole. The flange from the top wall is preferably anchored to the bottom vertebrae and the flange from the bottom wall is preferably anchored to the top vertebrae, relative to the disc space being treated, in such a case. One or more pairs of flanges of this type may be provided.

Preferably the side wall(s), top wall and bottom wall are joined together by stitching and/or other attachment techniques.

The side walls of the outer component may act as an annulus for the disc prosthesis. The side walls of the outer component may resists sideways expansion of the core, particularly when under compressive load. The side walls of the outer component may provide equivalent properties and/or behaviour to the annulus of a natural disc, for instance during compression and/or distraction and/or horizontal gliding and/or axial rotation and/or flexion and/or extension.

Preferably the inner component is provided snugly within the outer component. Preferably the top wall and/or bottom wall and/or one or more side walls of the outer component are dimensioned to contact the inner component.

Preferably the prosthetic disc is anchored to the spine away from the anterior side. Preferably the anchor positions are provided to either side of the anterior of the spine. One or more anchor positions may be used, preferably at least two are used on the vertebrae above and two on the vertebrae below the disc being replaced.

Preferably the prosthetic disc is anchored to the spine using one or more anchor locations provided thereon. Preferably one or more anchor locations are provided by a flange or flanges provided by the outer component. Preferably a flange has a length greater than the height of the side walls and/or greater then height of the disc space in which the prosthesis is to be used. The flanges may provided the anchor locations towards their ends. The flanges may have a width less than the width of a side wall.

In a preferred form, a flange is provided on the outer component in opposition to another flange provided on another part of the outer component. One of the flanges may be provided with a through aperture. One of the flanges may be provided with a reduced width and/or neck part. Preferably one of the flanges is interdigitated with the other by passing it though the hole. The flange from the top wall is preferably anchored to the bottom vertebrae and the flange from the bottom wall is preferably anchored to the top vertebrae, relative to the disc space being treated, in such a case. One or more pairs of flanges of this type may be provided.

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The outer component may be fastened at the anchor positions to one or more adjacent vertebra, for instance using fasteners. The fasteners may be one or more of bone screws, staples, sutures, nails or the like.

The first aspect of the invention may include any of the features, options or possibilities set out elsewhere in this document.

According to a second aspect of the invention we provide a kit for use in providing a disc prosthesis, the kit including a series of different sized prostheses, one or more of the prostheses including a core, the core being provided within an inner component, the inner component being provided within an outer component.

Preferably the kit includes different sized prostheses for different sized patients and/or different sized prostheses sized for different discs of the spine and particularly the lumber region thereof.

The second aspect of the invention may include any of the features, options or possibilities set out elsewhere in this document.

According to a third aspect of the invention we provide a surgical technique for providing a disc prosthesis, the technique including, removing at least part of the natural disc in a spine and inserting a disc prosthesis in the spine, the disc prosthesis comprising a core, the core being provided within an inner component, the inner component being provided within an outer component.

The technique may be performed anterially or posterially.

The technique may use a pre-assembled prosthesis. Preferably the outer component is inserted into the space and the inner component and core are then inserted. The inner component and core may be provided pre-assembled. A plurality of cores may be inserted into a single outer component.

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The third aspect of the invention may include any of the features, options or possibilities set out elsewhere in this document.

Various embodiments of the invention will now be described, by way of example only, and with reference to the accompanying drawings in which:-

Figure 1 is a plan view of a core suitable for use in the present invention;

Figure 2 is a cross-sectional front view of the core of Figure 1;

Figure 3 is a cross-sectional side view of the core of Figure 1;

Figure 4 is a plan view comparing the profile of a core according to the invention with a natural disc;

Figure 5 illustrates an inner jacket according to the present invention, prior to assembly; and

Figure 6 illustrates an outer jacket according to the present invention, prior to assembly.

The prior art contains examples of elastomeric discs, with the motion of the elastomer being contained by bonding it to metallic end-plates. In use, this results in high strains at the exterior faces of the disc and this in turn can give rise to tearing and eventually failure of the core.

The previously developed artificial intervertebral disc detailed in US-6093205, was developed particularly for the cervical region of the spine. The combination of an elastomeric inner core surrounded by a single embroidered outer textiles jacket has been shown to offer particular benefit in terms of the encapsulation preventing the initiation or propagation of any fissures in the elastomer component of the artificial disc.

To provide an optimised artificial disc for use in the lumbar region of the spine a number of further developments and improvements have been made. The artificial disc may act as a complete disc replacement, or a partial replacement, for instance for the nucleus. Anterior or posterior insertion is possible.

Firstly the core design has been designed specifically to provide optimal performance in the context of the lumbar region. Figure 1 represents a plan view of the core, in effect looking down on the disc as positioned in the spine, with the anterior top and posterior bottom in the figure. The core is octagonal with a greater width (left to right in the figure) than depth (top to bottom). The sides 10 are planar with rounded corners between them. The core is made of a long term implantable grade silicone material. A 50° Shore hardness material is preferred. Figure 2 is a cross-sectional view along axis A-A of Figure 1 and hence is a view of the posterior half of the core viewed from the anterior side. The planar upper surface 12 and lower surface 14 are visible. Figure 3 is a cross-sectional view along axis B-B of Figure 1 and hence shows the transition from anterior to posterior side. As can be seen, the thickness at the anterior edge 16 is less than the thickness at the posterior edge 18. Both upper 20 and lower 22 sides of the core increase symmetrically in thickness relative to the centreline of the core X-X during the transition from anterior edge 16 to posterior edge 18.

The optimised core design's plan profile 40 is seen in comparison with the plan profile 42 of the natural disc it is intended to replace in Figure 4. The naturally curved shape of the disc has been squared off in to an octagonal design. This allows easier design of the embroidery element of the disc. Additionally the anterior to posterior length, AP dimension, is reduced compared with the natural disc so as to keep the artificial disc away from the great vessels. When anchoring the device, as described in more detail below, centrally located anchoring on the anterior face, position X, of the vertebrae is avoided, with a preference for anchoring on the adjacent sides, positions Y.

Various alternative constructions of the core around this basic principle can be used. The core could be constructed as a single piece, in a manner such as that suggested above. Alternatively, particularly where minimally invasive surgery is required, the core may be formed of multiple core pieces which are inserted and assembled to form the overall core in-situ. Such core pieces can be individually inserted and assembled within a single inner jacket, but more preferably are individually wrapped in inner jackets which are then maintained in position by a single outer jacket.

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In more varied forms, the core can be formed of potentially tens or hundreds of small beads. The inner jacket would serve to maintain these in position. Cores formed of elastomer or hydrogel with elastomeric properties are also possible. As alternatives to the illustrated octagonal shape, hexagonal or rounded shapes can be used.

Around the core, an inner jacket is provided. This may be embroidered and/or woven. This is separate from a subsequent outer jacket. The inner jacket provides complete encapsulation of the core. As shown in Figure 5, the jacket is in the form of a first side wall 50a which is connected to a top wall 51 and bottom wall 52. The first side wall 50a is connected to a second side wall 50b in a first direction. In a second direction, the first side wall 50a is connected, in sequence to a third side wall 50c, fourth side wall 50d, fifth side wall 50e, sixth side wall 50f, seventh 50g and eighth 50h. These side wall are stitched to the top wall 51 and bottom wall 52 so as to give an octagonal box form to the inner jacket and close completely around the core.

The material used for the inner jacket uses densely packed fibres to define as smooth a surface as possible for the fabric. This is particularly desirable for the inner surfaces which contact the core. This ensures the most uniform contact surface area between the inner jacket and the elastomer core.

Connected to the eighth side wall 50h is the first of a series of additional elements also formed from the same embroidery. These additional elements, in sequence 55b, 55a, 55c, 55d, 55e, 55f, 55g and 55h are wrapped around the side walls 50 of the assembled inner jacket. As a result they form an additional ring of material around the side of the core. In effect this extra band of material strengthens the ability of the inner jacket to act as a natural annulus would and resist expansion sideways by the core when placed under compressive load. The additional elements can be secured with further stitching. The additional elements 55 could of course be provided by a suitably configured, but separate element to the element providing the walls 51, 52, 50.

The side walls 50 and additional elements 55 are provided with a length and height pattern intended to define an inner jacket which matches the length and height variation pattern of the core.

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An inner jacket provided in this way offers at least two key benefits.

Firstly it allows the jacket in contact with the core to have relatively low movement levels, whilst still enabling the overall desired level of movement for the artificial disc due to the outer jacket's presence and design. Low movement levels for the inner jacket mean that abrasion of the core is minimised. A single jacket would not achieve this.

Secondly, the inner jacket can be designed with properties ideal for its purpose, whilst allowing the outer jacket to be designed with properties ideal for its purpose. Thus the inner jacket aims to provide as dense and hence smooth a fabric surface as possible in contact with the core. In this way the risk of individual fibres protruding relative to the others is reduced. Protruding fibres can potentially cause wear due to the micro-motion of the jacket against the core in use. This is a particular potential issue in the context of the high loads encountered in the lumber region. Whilst such properties are desirable here, they are not consistent with those found to be desirable for the outer surface/outer jacket of the artificial disc. Using two separate jackets allows better optimisation in each case.

In a modified embodiment of the inner jacket, its properties may be tailored to facilitate tissue ingrowth into the space between the inner jacket and the core. The formation of a layer of tissue directly between the jacket and the core of the disc should be beneficial in reducing still further wear in the device. Because the dense fibre form used to provide the most smooth surface contacting the core is not the most conducive to tissue ingrowth, the make up of the inner jacket may be carefully controlled to assist.

By forming the inner jacket with a portion of the fibres or material formed of bio-absorbable material, as tissue ingrowth occurs the inner jacket can be partially absorbed to provide further room for the ingrowth. The non-bioabsorbable material of the inner jacket serves to provide the required structure for the inner jacket over its lifetime, supplemented by the assistance provided by the tissue itself. The use of quickly, moderately and slowly absorbed biomaterials in conjunction with non-

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absorbable materials can provide a gradual transition from the desired function being provided by the inner jacket alone to the point where it is shared between jacket and tissue. In some cases, an entirely bio-absorbable inner jacket may be provided. Various distributions for the non-absorbable and bio-absorbable material are possible in the inner jacket. The non-absorbable material may particularly form the outside of the inner jacket.

In addition to the core and inner jacket, an outer jacket is provided. A suitable outer jacket is illustrated in Figure 6. This is intended to substantially surround the inner jacket. The outer jacket has a bottom wall 60 and top wall 62, which are connected by side wall 64a. Further side walls 64b 64c are provided to one side of side wall 64a. Further side walls 64d, 64e are provided to the other side of side wall 64a. Attached to the top wall 62 is a sixth side wall 64f. The top, bottom and side walls are connected to one another by stitching. This leaves two sides of the outer jacket open, in effect the openings defined by edges 66 in one case and 68 in the other.

The edge 66 of the bottom wall 60 is provided with a flange 70. This has a hole 72 in it. The edge 66 of the top wall 62 is provided with a flange 74 which is thinner than flange 70, so as to be able to pass through the hole 72 in flange 70. Similarly, the edge 68 of the bottom wall 60 is provided with a flange 76. This has a hole 78 in it. The edge 68 of the top wall 62 is provided with a flange 80 which is thinner than flange 76, so as to be able to pass through the hole 78 in flange 76. To close the remaining two sides, therefore, flanges 70 and 74 and flanges 76 and 80 are interdigitated.

The flanges 70, 74, 76 and 80 are all significantly longer than the height of the disc space the artificial disc is to be used in. As a result the ends 82 of the flanges 70, 74, 76, 80 can be anchored to the vertebra above the disc replacement in the case of flanges 70 and 76 and to the vertebra below the disc replacement in the case of the flanges 74, 80.

The outer jacket has at least three beneficial functions.

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Firstly, it provides a jacket against the vertebral end-plates which is separate from the inner jacket that surrounds the core. This reduces micro-motion between the core and the inner jacket, but still means that the overall level of movement is as desired for the disc replacement as a whole.

Secondly, the outer jacket serves to effectively anchor the artificial disc in place. The interdigitation of the outer jacket effectively retains the inner jacket and core within it. Furthermore, the anchoring for the whole disc achieved through the fixation of the flanges to the vertebrae with screws, bone anchors or a similar type of fixation system is strong. It may be possible, in alternative embodiments to provide a more "free floating" device with the annulus of the disc sutured closed around the device to prevent migration.

Thirdly, the material of the outer jacket can be configured to give the desired structural properties, whilst also providing a relatively open structure for the material. This assists in providing good conditions for tissue ingrowth, both through the outer jacket and eventually through the inner jacket. The outer jacket can provided the desired access, but also act as a scaffold. As with the inner jacket, various combinations of bio-absorbable and non-absorbable materials can be used to assist this process.

The use of an inner jacket and outer jacket is also beneficial in that the use of multiple jackets allows the proportion of embroidery to elastomer to remain similar to that established as beneficial in the cervical disc.

In designing the artificial lumbar disc the aim has been to provide a disc having appropriate compressive stiffness. The decompression of the spinal cord through the opening of the disc space is one of the key principles in the relief of pain through disc replacement or fusion. To achieve this the artificial disc is provided with a compressive stiffness curve (force against displacement) similar or higher to the natural disc it is intended to replace. The properties of the core can be modified by doping or the like. For instance, the core may be provided with 13% barium sulphate.

Ideally, the artificial disc mimics as many of the motion stiffnesses as possible of a natural disc. Flexion/extension motions are both the most common and the largest (in terms of angle) motions that occur in the lumbar spine. This is the key stiffness which the above artificial disc seeks to match. The ability to carry shear and torsional loads on the disc itself should help protect the facet joints and is therefore also mimicked as far as possible.

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CLAIMS

1. A disc prosthesis including a core, the core being of elastomeric material, the core being provided within an inner component, the inner component being of fabric, the inner component being provided within an outer component, the outer component being of fabric, the inner component providing a smooth inner contact surface for the core, movement between the inner and outer components being facilitated in preference to movement between the inner component and core.

2. A disc prosthesis including a core, the core being provided within an inner component, the inner component being provided within an outer component.

3. A disc according to claim 2 in which the core is a single elastomeric component.

4. A disc according to claim 2 in which the core is formed of multiple elastomeric components, with each provided within its own inner component.

5. A disc according to any preceding claim in which the core provides a planar top surface and planar lower surface, the top and bottom surfaces not being parallel to one another, the separation of the top and bottom surfaces increasing from one side of the core to the other.

6. A disc according to any preceding claim in which the top surface and/or bottom surface of the core is octagonal and/or hexagonal and/or round and/or elliptic

7. A disc according to any of claims 2 to 6 in which the inner component is of fabric.

8. A disc according to any of claims 2 to 7 in which any movement, particularly sliding movement, within the disc is greater between the outer component and inner component than between the inner component and core.

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9. A disc according to any preceding claim in which the inner component is configured and/or formed of one or more materials intended to promote tissue growth.

10. A disc according to any preceding claim in which one or more materials used in the inner component are bio-absorbable.

11. A disc according to any of claims 2 to 10 in which uniform contact between the inner surface of the inner component and the core is provided.

12. A disc according to any of claims 2 to 11 in which a top wall of the inner component is connected to a side wall and hence to a bottom wall, with one or more further side walls being connected to the top wall and/or side wall and/or bottom wall.

13. A disc according to claim 12 in which the inner component is formed from an element including a side wall connected on one edge to a top wall and connected on an opposing edge to a bottom wall, the side wall being connected on one side edge to one other side wall and the side wall being connected on the other side edge to one or more other walls.

14. A disc according to any preceding claim in which the side walls of the inner component are contacted additional elements, provided by a continuous band extending around the side of the inner component

15. A disc in which the outer component is of fabric.

16. A disc according to any preceding claim in which the outer component is configured and/or formed of one or more materials intended to promote tissue growth, particularly tissue ingrowth through the outer component and/or between the inner component and the core and/or through the inner component.

17. A disc according to any preceding claim in which one or more materials used in the outer component are bio-absorbable.

18. A disc according to any preceding claim in which the outer component is formed from an element including a side wall connected on one edge to a top wall and connected on an opposing edge to a bottom wall, the side wall being connected on one side edge to two other side walls, the side wall being connected on the other side edge to two other side walls, a further side wall being connected to the opposite edge of the top wall or bottom wall to the edge to which the side wall linking the top wall and bottom wall is provided.

19. A disc according to any preceding claim in which one or more edges of the top wall and/or one or more edges of the bottom wall of the outer component are provided with flanges, the flanges providing anchor locations for attaching the outer component to one or more vertebrae.

20. A kit for use in providing a disc prosthesis, the kit including a series of different sized prostheses, one or more of the prostheses including a core, the core being provided within an inner component, the inner component, the inner component being provided within an outer component.

21. A kit according to claim 20 wherein the disc prosthesis is provided according to any of claims 1 to 19.

22. A surgical technique for providing a disc prosthesis, the technique including, removing at least part of the natural disc in a spine and inserting a disc prosthesis in the spine, the disc prosthesis comprising a core, the core being provided within an inner component, the inner component, the inner component being provided within an outer component.

23. A surgical technique according to claim 22 wherein the disc prosthesis is provided according to any of claims 1 to 19.

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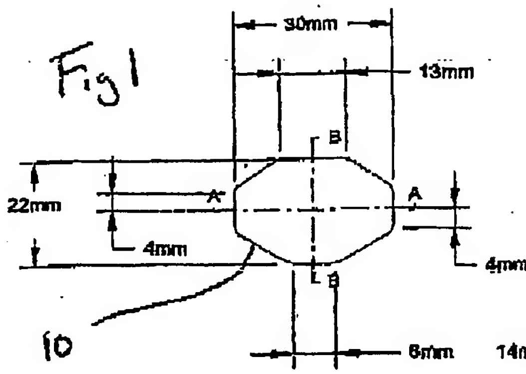
Fig1



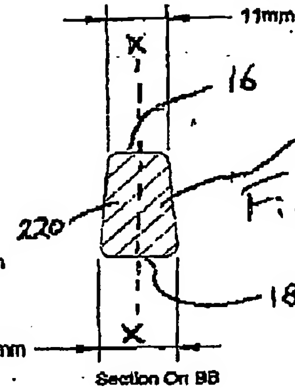
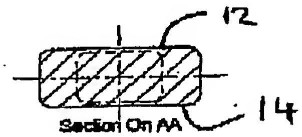


Fig3

Fig2



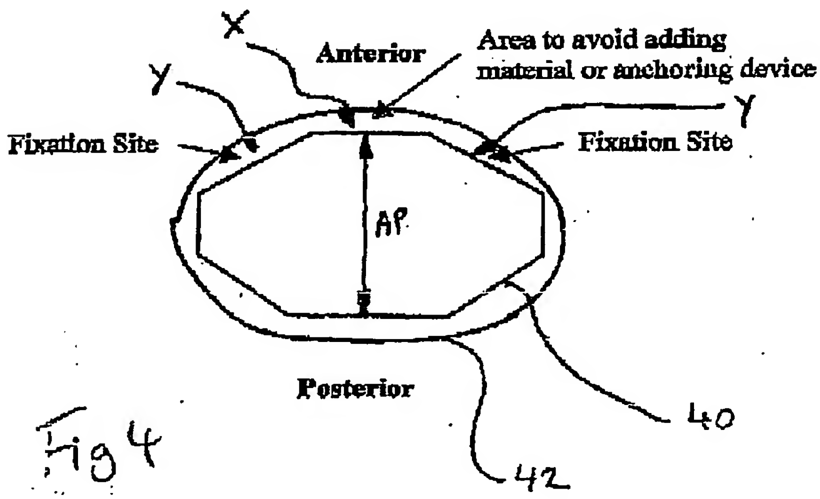


Fig4

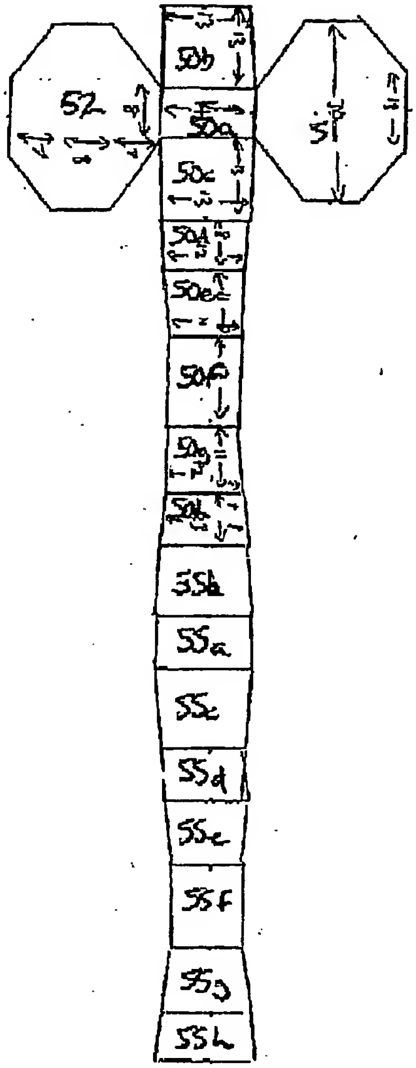


Fig 5

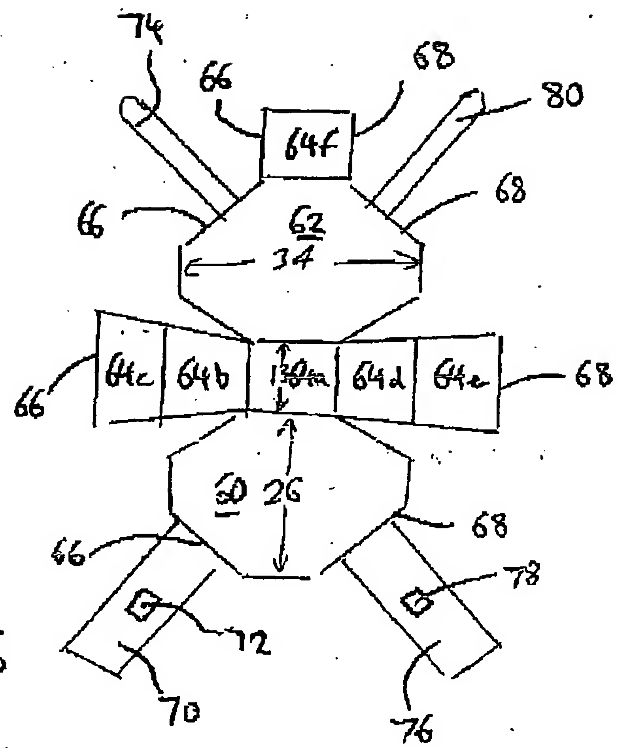


Fig 6

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